

<b>Notice of Allowability</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/810,601	DONOVAN, STEPHEN	
	Examiner Chih-Min Kam	Art Unit 1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTO-85) or other appropriate communication will be mailed in due course. THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS. This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1.  This communication is responsive to 3/9/04.
2.  The allowed claim(s) is/are 22 and 26-30.
3.  The drawings filed on \_\_\_\_\_ are accepted by the Examiner.
4.  Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a)  All
  - b)  Some\*
  - c)  None
  1.  Certified copies of the priority documents have been received.
  2.  Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3.  Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.  
**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

5.  A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
6.  CORRECTED DRAWINGS ( as "replacement sheets") must be submitted.
  - (a)  including changes required by the Notice of Draftperson's Patent Drawing Review ( PTO-948) attached
    - 1)  hereto or 2)  to Paper No./Mail Date 4/21/03.
  - (b)  including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7.  DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

#### Attachment(s)

1.  Notice of References Cited (PTO-892)
2.  Notice of Draftperson's Patent Drawing Review (PTO-948)
3.  Information Disclosure Statements (PTO-1449 or PTO/SB/08).  
Paper No./Mail Date \_\_\_\_\_
4.  Examiner's Comment Regarding Requirement for Deposit of Biological Material
5.  Notice of Informal Patent Application (PTO-152)
6.  Interview Summary (PTO-413),  
Paper No./Mail Date 6/07/04.
7.  Examiner's Amendment/Comment
8.  Examiner's Statement of Reasons for Allowance
9.  Other \_\_\_\_\_.

*Christopher S. F. Low*  
CHRISTOPHER S. F. LOW  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1800

An Examiner's Amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Stephen Donovan on June 7, 2003.

**Examiner's Amendments to the Claims:**

Claims 22 and 26-30 have been amended as follows:

22. (Currently amended) A method for treating a gonadotrophin related illness in a mammal, said method comprises the steps of:

(I) administering to the mammal a therapeutically effective amount of an agent, the agent comprises:

(a) [a] an LH<sub>N</sub> which comprises (i) a light chain component, [comprising a light chain] an L-chain[.] of a botulinum toxin, a butyricum toxin, or a tatani toxin and (ii) a translocation component, [comprising a heavy chain] an H<sub>N</sub> of a botulinum toxin, a butyricum toxin, or a tatani toxin; and

(b) a targeting component which comprises a gonadotrophin-releasing hormone (GnRH) or GnRH analog, wherein the LH<sub>N</sub> is covalently coupled to the GnRH or GnRH analog, and wherein the targeting component selectively binds to a GnRH receptor; and

(II) alleviating the gonadotrophin related illness by lowering the level of a gonadotrophin secretion, wherein the gonadotrophin related illness is selected from the group consisting of breast cancer, prostate cancer, pancreatic cancer, and endometrial cancer[,

thereby treating a gonadotrophin related illness by lowering the level of a gonadotrophin secretion].

26. (Currently amended) The [agent] method according to claim 22 wherein the light chain component of the agent decreases the release of a hormone from a cell.

27. (Currently amended) The [agent] method according to claim 22 wherein the light chain component of the agent [comprises] is the light chain of [a] botulinum toxin type A, B, C<sub>1</sub>, D, E, F, or G.
28. (Currently amended) The [agent] method according to claim 22 wherein the light chain component of the agent [comprises] is the light chain of [a] botulinum toxin type A.
29. (Currently amended) The [agent] method according to claim 22 wherein the translocation component of the agent [comprises a heavy chain] is the H<sub>N</sub> of [a] botulinum toxin type A, B, C<sub>1</sub>, D, E, F, or G.
30. (Currently amended) The [agent] method according to claim 22 wherein the translocation component of the agent [comprises a heavy chain] is the H<sub>N</sub> of [a] botulinum toxin type A.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (571) 272-0948. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on (571) 272-0951. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 308-4227 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Chih-Min Kam, Ph. D. *cmk*  
Patent Examiner

\*\*\*

June 7, 2004

*Christopher S. F. Low*  
CHRISTOPHER S. F. LOW  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600